**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| PATRICIA MUNION and DAVID MUNION,<br><br>Plaintiffs,<br><br>vs.<br><br>ADVANCED MEDICAL OPTICS, INC., ET. AL.<br><br>Defendant. | CIVIL ACTION NO. 07-CV-5377<br>JUDGE JOSEPH H. RODRIGUEZ<br><br>ORAL ARGUMENT REQUESTED |

**DEFENDANTS' MEMORANDUM IN CONNECTION WITH THE SEALING OF CERTAIN EXHIBITS FURNISHED IN CONNECTION WITH PLAINTIFFS' OPPOSITION TO ALLERGAN'S MOTION FOR SUMMARY JUDGMENT**

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## INTRODUCTION

Defendants Abbott Medical Optics, Inc. (f/k/a Advanced Medical Optics Inc.) ("AMO") and Allergan submit this brief in connection with Plaintiffs' Motion pursuant to Local Rule 5.3(c) to Seal certain exhibits (Pacer Document No. 149). In sum, in their opposition to a motion for summary judgment filed by Allergan, Inc. (Pacer Document Nos. 147 and 148), plaintiffs relied upon some thirty-one (31) Exhibits, many of which were documents designated as confidential and produced by AMO and/or Allergan pursuant to this Court's Discovery Confidentially Order (Pacer Document No. 18). Defendants respectfully submit that the following four (4) of these Exhibits should remain under seal and not be publicly disclosed:

> Exhibit 6: "Allergan Complete Worldwide Integrated Development Plan dated December 1, 1998, updated March 15, 2002";
>
> Exhibit 15: "Root Cause Assessment for Acanthamoeba Keratitis Risk Associated with Use of COMPLETE®MoisturePLUS® MultiPurpose Solution prepared by Dr. John M. Lally of AMO dated October 12, 2007";
>
> Exhibit 24: "Exhibit 2 marked at the Deposition of James Cook dated December 3, 2009, COMPLETE® Formulation Charts"; and
>
> Exhibit 25: "Allergan Complete Upgrade C Regulatory Plan, May 2001."

Each of these four Exhibits contains proprietary and confidential information, including, among other things, the identity of the formula and ingredients of contact lens care solution products manufactured by AMO or its subsidiaries. These Exhibits also contain privileged and confidential information of great significance to AMO, the disclosure of which could clearly damage AMO and its business interests. As set forth below, the standards of Local Civil Rule 5.3(c) are met with regard to each of these Exhibits, which must be maintained under seal.

Defendants do not object to plaintiffs' request for the de-designation of the other Exhibits identified in plaintiffs' papers. This is not to say that the materials within those Exhibits, furnished in accord with the Court's Discovery Confidential Order, are not legitimately confidential; however, with the threshold of Local Civil Rule 5.3(c) as high as it is, and with the significance of these four Exhibits – Nos. 6, 15, 24, and 25 – as great as it is, AMO's focus is to protect from public disclosure only those Exhibits most significant to its business interests. The information contained in these four Exhibits is highly confidential, and the public disclosure of these documents would cause serious harm to AMO.

## LEGAL ARGUMENT

### I. LEGAL STANDARDS APPLICABLE TO THIS MEMORANDUM

This application is governed by Local Civil Rule 5.3(c). The Rule sets forth the standards that must be met with respect to the sealing of documents filed with the Court, and requires a showing of:

(a) the nature of the materials or proceedings at issue;

(b) the legitimate private or public interest which warrants the relief sought;

(c) the clearly defined and serious injury that would result if the relief sought is not granted; and

(d) why a less restrictive alternative to the relief sought is not available.

These requirements are met in this case. They are addressed below and in the supporting Affidavit of James Cook, who serves as Senior Manager, Product Development, Corneal, for Abbott Medical Optics, Inc. (f/k/a/ Advanced Medical Optics, Inc.).

As a threshold matter, the four Exhibits at issue were all designated as confidential and produced pursuant to the Discovery Confidentiality Order entered in this case. Each contains information related to the formulas of certain AMO products. They also contain information that is proprietary and confidential to AMO, including vital trade secrets of the company and/or self-critical root cause analysis, the disclosure of which could impair AMO's business interests. AMO respectfully submits that these four Exhibits warrant protection from public disclosure.

## II. EACH OF THE FOUR EXHIBITS CONTAINS HIGHLY CONFIDENTIAL FORMULAS THAT ARE PROTECTED TRADE SECRETS OF AMO.

### A. The Nature of the Materials or Proceedings at Issue.

The product at issue in this lawsuit, COMPLETE MoisturePLUS® Multi-Purpose Solution (MPS), is one of a family of contact lens care products developed and marketed by Allergan (before the spin-off of AMO in 2002) or by AMO (after 2002). See Cook Affidavit, ¶ 8. In many ways, the formulas in the product family are similar, containing many of the same ingredients in the same proportions, and with each formula building on its predecessors. Id.

Exhibit 6, at page 14, identifies the formula for COMPLETE MoisturePLUS® MPS (also know as Complete C), as well as other formulas which were considered for use and which vary only slightly from the final formula. In addition, at pages 17-18, the Exhibit provides a narrative history of the formulas in the COMPLETE® family, and shows how each formula varied from its predecessor. Id., ¶ 9.

Exhibits 15 and 24 identify the formulas for *all* the products in the COMPLETE® family of MPS. Many of these formulas are still marketed by AMO in various countries. Id., ¶ 11. Exhibit 25 also identifies the formula for COMPLETE MoisturePLUS® MPS, as well as two other formulas which were considered. In addition, Exhibit 25 identifies the formula for the predecessor to COMPLETE MoisturePLUS® MPS (also known as Complete B). Id., ¶ 10.

These documents are unique among those relied upon by plaintiffs in so far as they contain the formulas for the manufacture of AMO products.

### B. A Legitimate Private or Public Interest Warrants the Relief Sought.

As outlined in the Affidavit of Mr. Cook, each of the Exhibits contains trade secrets. There is a legitimate private and public interest against the public disclosure of trade secret formulas owned by a business. New Jersey follows the common law with regard to trade secrets,

and protects the interests of the companies that do business within the State. New Jersey courts routinely protect confidential formulas from public disclosure.

In Hammock by Hammock v. Hoffman-LaRoche, Inc., 142 N.J. 356, 383-384 (1995), and Ingersoll Rand Co. v. Ciavatta, 110 N.J. 609, 636 (1988), the New Jersey Supreme Court cited with approval the definition of "trade secret" found in the Restatement of Torts §757 comment b (1939):

> A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.

This language mirrors the language in the Discovery Confidentiality Order in this case (Pacer Document No. 16), which includes four separate definitions of what constitutes a trade secret (FDA, state criminal statue, common law, and Restatement 3rd.). The courts in New Jersey also endorse reliance on the six factors listed in the Restatement that help to determine whether a particular idea or information is a trade secret:

> (1) the extent to which the information is known outside of the business; (2) the extent to which it is known by employees and others involved in the business; (3) the extent of measures taken by the owner to guard the secrecy of the information; (4) the value of the information to the business and its competitors; (5) the amount of effort or money expended in developing the information; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Hammock by Hammock , 142 N.J. at 384; Ingersol, 110 N.J. at 637.

The Appellate Division in Rycoline Prods., Inc. v. Walsh, 334 N.J. Super. 62, 75 (App. Div.), certif. den. 165 N.J. 678 (2000), acknowledged the trade secret protections afforded to formulas, observing that the "selection of particular ingredients for a formula from a vast array of

publicly known possible ingredients may result in trade secret protection for the specific selection made." The court also stated that a product does not have to represent a "great step in imagination" to constitute a trade secret. Id. Moreover, the fact that a formula resulted from efforts to reverse-engineer a competitor's product does not preclude trade secret status for that formula. Id. at 73; see also Sun Dial Corp. v. Rideout, 16 N.J. 252, 257 (1954); Johnson v. Benjamin Moore & Co., 347 N.J. Super. 71, 95 (App. Div. 2002); Nat. Starch & Chem. v. Parker Chem., 219 N.J. Super. 158, 160-162 (App. Div. 1987).

As set forth in Mr. Cook's Affidavit, the formulas found in these four Exhibits are not known outside of AMO, and are not public. See Cook Aff., ¶ 12. AMO's competitors do not have access to the formulas or makeup of AMO's products. Indeed, while some of the ingredients are disclosed on the product label, the amount of each ingredient is tightly controlled to avoid disclosure. Id. Further, it is very difficult to precisely "reverse engineer" a formula. Even if one obtained a bottle of a product, the precise amount of each ingredient could not be determined. Id. This information, however, is plainly set forth in these Exhibits.

The formulas or makeup of AMO's products are not even known by all of AMO's employees. Access to this information is restricted, and only certain employees with appropriate responsibilities and clearance have knowledge of product formulas. Id., ¶ 14. AMO's employees are subject to confidentiality agreements and access to the formulas are restricted. Not surprisingly, AMO's competitors also protect their formulas, and the precise formulation of competitor contact lens products is not available to AMO. Id., ¶ 13.

The formulas are of great value to AMO because it is the composition of its products that create competitive advantages for AMO in the marketplace. Id., ¶ 16. The formulas and the products they are used to create are unique and proprietary to AMO.

The development of these formulas took years and involved the enormous effort of many AMO employees. Id., ¶ 17. The disclosure of the Exhibits would undermine years of research and development. Id. If the formulas were to make their way into the hands of others with the appropriate training and scientific know-how, AMO's work product and its products could be counterfeited, severely undermining AMO's position in the marketplace. Id., ¶ 18.

Because each formula in the family has many elements in common with the others, even the disclosure of one of the formulas places the entire family in jeopardy. Id., ¶ 19. For example, although COMPLETE MoisturePLUS® MPS is no longer marketed, it is sufficiently similar in some respects that disclosure of its precise formula would jeopardize the other formulas in the COMPLETE® family that are currently marketed. The series of formulas also reveals a development philosophy of AMO that would be of interest to competitors and the disclosure of which would harm AMO. Id.

Public disclosure of these Exhibits would allow anyone with an internet connection and Pacer account to review and study these Exhibits, thereby bypassing years of professional and scientific investment. The Courts have been cognizant of the need to protect confidential formulas from public disclosure, recognizing that competitors abound in the marketplace. See Cima Labs, Inc. v. Actavis Group HF, 2007 U.S. Dist. LEXIS 41516, 15 (D.N.J. June 7, 2007) (holding that a showing that "trade secrets would be lost if competitors gained access to the materials . . . satisfied the factors set forth in L. Civ. R. 5.3(c)(2)"). (A copy of this unpublished decision is attached hereto at Tab 1.)

As indicated above, looking at the six factors outlined in the Restatement of Torts §757 comment b, the formulas found in the four Exhibits at issue are trade secrets. Indeed, product formulas are at the cornerstone of trade secret analysis. AMO has a legitimate public and private

interest that warrants an Order sealing Exhibits 6, 15, 24 and 25. Public disclosure of these Exhibits would adversely impact AMO's business by placing its trade secrets in the public domain. See Cook Aff., ¶ 20. AMO operates in a highly competitive marketplace and if the make-up of its products are publicly available they will necessarily suffer serious harm and AMO will be at a competitive disadvantage. AMO's legitimate expectation that the formulas and ingredients of its product will not be publicly disclosed transcends this case.

Moreover, the public disclosure of trade secrets would be detrimental to the development of science and innovation. This is true here, but equally important in other contexts. A business has the right to expect that its proprietary product formulas will not be made available to competitors and the public at-large during the course of a lawsuit. Enormous mischief could result if the mere filing of a lawsuit could trigger the public disclosure of a company's formulas and trade secrets.

### C. Clearly Defined and Serious Injuries Will Result if the Relief Sought is Not Granted.

Some of the injuries that would befall AMO are discussed above, and they are addressed in the Cook Affidavit. In addition, the disclosure of formulas would cause serious harm because a competitor could use the information to support its sales and subvert the business interests of AMO. See Cook Aff., ¶ 22. Also, public disclosure of the documents would allow a competitor or unknown party to use the information to make new products or improve their own products, thereby putting AMO at a competitive disadvantage. Id., ¶ 23.

The market for contact lens solutions is competitive. Innovations like product formulations are closely guarded. The formulas in effect *are* the products. Public disclosure of the formulas would have a deleterious and potentially wide-ranging, negative impact upon AMO. On a broader scale, disclosure of formulas would set a damaging precedent for businesses

operating in New Jersey. This is not an issue of production to an adversary in litigation, but publication to the world. Based on the clearly defined and serious injuries that AMO would face if the relief sought is not granted, AMO respectfully submits that these four Exhibits be sealed. See Mars, Inc. v. JCM American Corp., 2007 U.S. Dist. LEXIS 9819, 5-9 (D.N.J. February 13, 2007) (internal quotations omitted)(holding that, under the facts of that case, sealing confidential business documents under Local Rule 5.3 outweighed the public interest in the documents and Judge Schneider stated that "Courts generally protect materials containing trade secrets or other confidential research, development, or commercial information to prevent harm to a litigant's standing in the marketplace.") (A copy of this unpublished decision is attached hereto at Tab 2.)

**D. A Less Restrictive Alternative to the Relief Sought Is Not Available.**

To the best of AMO's knowledge, there are no less restrictive alternatives to the relief sought other than sealing the Exhibits.

## III. EXHIBIT 15 ALSO CONTAINS HIGHLY CONFIDENTIAL, PRIVILEGED, SELF-CRITICAL ANALYSIS PROTECTED FROM PUBLIC DISCLOSURE

In addition to containing the formulas for the composition of the product, which is a protected trade secret, Exhibit 15 contains a confidential, self-critical analysis that is protected from public disclosure. This is a separate basis for the sealing of this Exhibit. The following demonstrates that Exhibit 15 needs to be sealed from public disclosure under Local Rule 5.3(c).

### A. The Nature of the Materials or Proceedings at Issue.

Exhibit 15 contains a confidential, self-critical root cause analysis protected from public disclosure. See Cook Aff., ¶ 24. The Exhibit was generated after COMPLETE MoisturePLUS® MPS was voluntarily withdrawn from the market. In view of the history and magnitude of pharmaceutical and medical device litigations in this country, it is beyond question that AMO anticipated litigation, and prepared Exhibit 15 with that knowledge. Id.,¶ 25.

The very cover page of Exhibit 15 states that it contains highly confidential information and even requests that FDA withhold producing the document in response to any Freedom of Information Act ("FOIA") requests. AMO understands that the FDA has honored that request. The document has been turned over in this litigation only pursuant to court Order and thereupon only pursuant to a Discovery Confidentiality Order.

The banner on the document, which reads as follows, underscores the expectations of confidentiality:

> **Because this submission contains highly confidential commercial information and trade secrets, AMO requests that it be withheld from disclosure under the Freedom of Information Act pursuant to 21 C.F.R. § 20.61. We further request that should FDA tentatively determine that any portion of the submission is disclosable in response to a request under the Freedom of Information Act, we be provided with an opportunity for prior consultation in accordance with C.F.R. § 20.47.**

This Root Cause Assessment was conducted subsequent to the recall under the attorney work product and attorney client privileges in the context of litigation for the purpose, among other things, of evaluating and responding to allegations filed in state and federal courts. Its submission by AMO to the FDA for the purpose of cooperation does not constitute a waiver of such privileges.

Exhibit 15 has been confidential from the moment of its creation, has been disclosed only pursuant to court Order, and must remain under seal.

**B. Legitimate Private or Public Interests Warrant the Relief Sought.**

There is a legitimate public interest not only in sealing self-critical root cause documents, but also in not publishing them on-line during the course of litigation. The self-critical analysis privilege has been recognized in a variety of cases within the District of New Jersey. This privilege is "essential to the free flow of information and . . . the free flow of information is essential to promote recognized public interests." Harding v. Dana Transp., Inc., 914 F. Supp. 1084, 1100 (D.N.J. 1996) (citing Note, The Privilege of Self-critical Analysis, 96 Harv. L. Rev. 1083, 1087 (1983)). To determine whether the self-critical analysis privilege is applicable, courts analyze the following:

> (1) whether the information is the result of a self-critical analysis undertaken by the party seeking protection, (2) the extent to which the information is available from other sources, (3) the degree of harm the litigant will suffer from the information's unavailability, (4) the possible prejudice to the party asserting the privilege, (5) the public interest in preserving the free flow of the type of information sought, and (6) whether the information is of the type whose flow would be curtailed if discovery were allowed.

Bracco Diagnostics, Inc. v. Amersham Health, Inc., 2006 U.S. Dist. LEXIS 75359, 8-9 (D.N.J. 2006). (A copy of this unpublished decision is attached hereto at Tab 3.)

Application of these factors demonstrates that Exhibit 15 must be protected from public disclosure under the self-critical analysis privilege. First, there is no doubt that Exhibit 15 was created as a result of AMO's self-critical analysis and investigation, which meets the first criterion. Second, because the plaintiffs already have a copy of Exhibit 15, the second factor is not applicable. The third and fourth factors favor sealing the Exhibit because plaintiffs will suffer no harm from sealing the document, but AMO would suffer significant prejudice from its public disclosure. Such public disclosure could discourage companies from conducting investigations of this nature if the results were to be subject to publication on-line, as would be the case if this Exhibit were de-designated. The free exchange of information (and analysis and evaluation thereof) could be frustrated if the results were made publicly available.

Here, AMO communicated with FDA as to its findings. AMO provided this information with the understanding that FDA would keep its work product confidential and protected from disclosure pursuant to FOIA. AMO submits that the request to de-designate Exhibit 15 should not subvert the protections that have attached to the document since its initial preparation and production – protections that have been honored by FDA.

As to the fifth factor, the public has a significant interest in preserving the free flow of the type of information at issue in Exhibit 15. "Many courts have analogized the public's interest in maintaining the free flow of information of this type and invocation of the self-critical analysis privilege to Fed. R. Evid. 407, more commonly known as the subsequent remedial measures rule." Bracco Diagnostics, 2006 U.S. Dist. LEXIS 75359 at 16-17. The Bracco court held:

> [T]he Court finds that it is in the public interest for organizations, when faced with a possible violation of law or government regulation intended to protect the public, to attempt to expeditiously determine the causes and results, and correct them accordingly. The flow of information of this type is crucial to

> protection of the public-at-large from so-called 'breakdowns in the system.'

Id. at 19-20. Notably, Bracco dealt with an investigative report regarding the defendant Amersham Health, Inc.'s sales and marketing practices of pharmaceuticals to assess compliance with FDA rules and to ensure safety. Id. at 20-21.

Finally, the sixth factor also favors sealing Exhibit 15 because it contains the type of information "whose flow would be curtailed if discovery were allowed." Id. at 22. The District of New Jersey has held that one of purposes of the self-critical analysis privilege includes preventing "the chilling effect upon such self analysis which would result from complete disclosure." Id.

In short, there are legitimate public and private interests to keeping Exhibit 15 under seal.

### C. Clearly Defined and Serious Injuries Will Result if the Relief Sought Is Not Granted.

In addition to the injuries listed above, public disclosure of the self-critical root cause analysis could have far reaching consequences and could undermine efforts by businesses to investigate any potential concerns they may have regarding their products. Furthermore, if Exhibit 15 is in the public domain, and available on the Court's website, it would be easily obtainable by AMO's competitors and could be used against AMO by salespersons throughout this highly competitive industry. AMO took the steps it believed were appropriate and necessary in performing this self-critical analysis. FDA has the Exhibit and kept it from public disclosure. De-designating the Exhibit would cause injury to AMO as a result of the highly competitive industry in which it competes. See Charles F. Shipes v. BIC Corporation, 154 F.R.D. 301, 307 (M.D. Ga. 1994) (applying the self-critical analysis privilege to confidential self evaluation documents created by a manufacturer for submission to the Consumer Product Safety Commission).

**D. A Less Restrictive Alternative to the Relief Sought Is Not Available.**

AMO is not aware of a less restrictive alternative to sealing Exhibit 15.

## CONCLUSION

For the foregoing reasons, and in order to protect the information designated by the parties to be confidential, AMO and Allergan respectfully request that the Court maintain Exhibits 6, 15, 25 and 25 under seal.

Respectfully submitted,

Dated: July 6, 2010

*/s/ David J. Cooner*

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that true copies of this Memorandum in Support of Plaintiffs' Motion to Seal, with supporting papers were caused to be served on July 6, 2010, upon the following:

**Via *ECF*:**

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*/s/ David J. Cooner*
David J. Cooner

# TAB 1

**CIMA LABS, INC. and SCHWARZ PHARMA, INC., Plaintiffs, v. ACTAVIS GROUP HF, ACTAVIS, INC. and ACTAVIS ELIZABETH, LLC, Defendants. CIMA LABS, INC. and SCHWARZ PHARMA, INC., Plaintiffs, v. PAR PHARMACEUTICAL COMPANIES, INC., PAR PHARMACEUTICAL, INC. and KALI LABORATORIES, INC., Defendants.**

**Civ. No. 07-893 (DRD), Civ. No. 06-1970 (DRD) (Consolidated with 06-1999 (DRD))**

**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY**

***2007 U.S. Dist. LEXIS 41516***

**June 7, 2007, Decided**
**June 7, 2007, Filed**

**NOTICE:** [*1] NOT FOR PUBLICATION

**CORE TERMS:** patent, discovery, reexamination, filler, generic, infringement, consolidation, compression, notice, consolidate, alprazolam, non-direct, patent infringement, seal, judicial economy, consolidated, manufacture, infringe, dosage, question of law, infringed, weigh, trial date, disintegrating, certification, disadvantage, pretrial, simplify, rapidly, orally

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**JUDGES:** DICKINSON R. DEBEVOISE, U.S.S.D.J.

**OPINION BY:** DICKINSON R. DEBEVOISE

**OPINION**

*DEBEVOISE, Senior District Judge*

I. *PROCEDURAL HISTORY*

Plaintiffs, Cima Labs, Inc. ("Cima") and Schwarz Pharma, Inc. ("Schwarz Pharma") (collectively, "Plaintiffs") each instituted patent infringement **[*2]** actions against defendants Par Pharmaceutical Companies, Inc., Par Pharmaceutical, Inc., and Kali Laboratories, Inc. (the "Par/Kali Defendants") alleging infringement of *U.S. Patent No. 6,024,981* (the "*'981 patent*") and *U.S. Patent No. 6,221,392* (the "*'392 patent*") (the "patents"). By

stipulation and order dated January 25, 2007, those cases were consolidated (the "Par case"). Subsequently, on February 23, 2007, Plaintiffs instituted a patent infringement action against defendants, Actavis Group hf [1], Actavis, Inc., and Actavis Elizabeth LLC, alleging infringement of the patents (the "Actavis case").

1 The present motion to dismiss was filed by Actavis, Inc. and Actavis Elizabeth LLC ("Actavis") and does not include Actavis hf.

There are currently four motions pending before the court: (1) Actavis's motion to dismiss the Complaint in the Actavis case pursuant to *Fed. R. Civ. P. 12(b)(6)*; (2) Actavis's motion to seal portions of the brief and exhibits filed in its motion **[*3]** to dismiss; (3) Cima's motion to temporarily stay the proceedings in both the Actavis case and the Par case; and (4) Cima's motion to consolidate the Actavis case and the Par case. For the reasons set forth below, Actavis's motion to dismiss will be denied and its motion to seal will be granted, and Cima's motion to consolidate and motion to stay will be granted.

II. *BACKGROUND*

The Actavis case and the Par case are patent infringement actions arising under the Hatch-Waxman Act. In both cases the defendants have sought approval from the FDA to sell a generic version of the prescription drug NIRAVAM TM , an alprazolam product.

The invention covered by both of the patents is known to produce an in-mouth disintegrable dosage form for the delivery of drugs. (Col. 1, ll. 12-13). The invention relates to a hard, compressed, rapidly dissolvable dosage form adapted for direct oral dosing. (Col. 2, ll. 5-7). The dosage form includes an active ingredient and a matrix. (Col. 2, ll. 7-8). The matrix is composed of at least a non-direct compression filler and a lubricant. (Col. 2, ll. 8-9). The dosage form is adapted to rapidly dissolve in the mouth of a patient and thereby liberate the active **[*4]** ingredient. (Col. 2, ll. 9-11).

Plaintiffs' complaint in the Actavis case (the "Complaint") alleges the following:

On February 15, 2000, the United States Patent and Trademark Office (the "PTO") issued the *'981 patent*, entitled "Rapidly Dissolving Robust Damage Form." (Compl. P 13). An *ex parte* reexamination of the *'981 patent* was requested on or about August 22, 2005, and reexamination was ordered on or about October 7, 2005. (*Id.* at P 14). A second *ex parte* reexamination was filed on or about September 7, 2006, and reexamination was ordered on or about September 28, 2006. (*Id.*). The two reexaminations were consolidated on or about January 8, 2007. (*Id.*). By way of assignment, Cima owns all rights, title, and interest in and to the *'981 patent*, including the right to sue and recover for patent infringement. (*Id.* at P 15).

On April 24, 2001, the PTO issued the *'392 patent*, entitled "Rapidly Dissolving Robust Damage Form." (*Id.* at P 16). An *inter partes* reexamination was filed on July 28, 2006, and reexamination was ordered on or about September 13, 2006. (*Id.* at P 17). By way of assignment, Cima owns all rights, title, and interest in and to the **[*5]** *'392 patent*, including the right to sue and recover for patent infringement. (*Id.* at P 18).

Schwarz Pharma is the exclusive licensee to the *'981* and *'392 patents* for alprazolam orally disintegrating tablets in the United States. (*Id.* at P 19). Under the exclusive license, Cima manufactures NIRAVAM TM , an alprazolam product, for Schwarz Pharma. (*Id.*). The *'981* and *'392 patents* are listed in the Orange Book (formerly entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*) as covering NIRAVAM TM , alprazolam orally disintegrating tablets on 0.25 mg, 0.5 mg, 1 mg, and 2mg dosages. (*Id.* at P 20).

Actavis Elizabeth LLC submitted an Abbreviated New Drug Application ("ANDA"), No. 78-561, to the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug and Cosmetic Act, *21 U.S.C. § 355(j)* (the "ANDA"). (*Id.* at P 21). Actavis filed the ANDA seeking the approval of the FDA necessary to engage in the commercial manufacture, use, offer for sale and sale of generic versions of alprazolam orally disintegrating tablets in 0.25 mg, 0.5 mg, 1mg, and 2 mg dosages. (*Id.*).

No earlier than January 12, 2007, Plaintiffs **[*6]** received a letter from Actavis notifying them that the ANDA containing a Paragraph IV Certification had been submitted to the FDA (the "Paragraph IV Notice Letter"). (*Id.* at P 22). The Paragraph IV Notice Letter and the ANDA allege that the *'981* and *'392 patents* are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the generic versions of alprazolam orally disintegrating products for which Actavis seeks FDA approval. (*Id.*).

Plaintiff's allegations in Counts One and Two are identical with respect to each patent. Plaintiffs allege that Actavis's submission of the ANDA to the FDA constitutes infringement of the *'981* and *'392 patents* under *35 U.S.C. § 271(e)(2)(A)*. (*Id.* at P 25, 31). Plaintiffs also allege that Actavis's manufacture, use, offer for sale and/or sale of its proposed generic versions for which Actavis seeks approval from the FDA under the ANDA will infringe, contribute to the infringement of and induce infringement of one or more of the claims of the *'981* and *'392 patents*. (*Id.* at P 26, 32). Plaintiffs further allege that Actavis was aware at the time of submission of the ANDA, and continues to be **[*7]** aware, that the

proposed generic versions, if approved, will be made, used and/or sold in contravention of Plaintiffs' rights in and to the *'981* and *'392 patents*. (*Id.* at P 27, 33). Plaintiffs allege that the conduct by Actavis renders this case "exceptional" as described in *35 U.S.C. § 285*. (*Id.* at P 28, 34).

In their prayer for relief, Plaintiffs seek: (1) a judgment that Actavis has infringed the *'981* and *'392 patents*; (2) an order pursuant to *35 U.S.C. § 271(e)(4)(A)* decreeing the effective date of any approval of the ANDA be subsequent to the date of the last to expire of the patents; (3) a preliminary and permanent injunction pursuant to *35 U.S.C. § 271 (e)(4)(B)*; (4) monetary relief and damages pursuant to *35 U.S.C. § 284*; (5) a declaration that this case is exceptional under *35 U.S.C. § 271(e)(4)(C)* and *35 U.S.C. § 285*; and (6) attorneys' fees and costs. (Compl. at p. 7-8).

The complaints filed in the consolidated Par case contain similar allegations. Each complaint alleges infringement based on the Par/Kali Defendants' submissions **[*8]** of ANDAs to the FDA seeking approval of the FDA necessary to engage in the commercial manufacture, use, and sale of generic versions of alprazolam tablets.

III. *DISCUSSION*

A. *Actavis's Motion to Dismiss*

1. *Standard for Dismissal under Fed. R. Civ. P. 12(b)(6)*

Dismissal of a complaint pursuant to *Rule 12(b)(6)* is proper "only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Hishon v. King & Spalding, 467 U.S. 69, 73, 104 S. Ct. 2229, 81 L. Ed. 2d 59*. Allegations contained in the Complaint will be accepted as true, *Cruz v. Beto, 405 U.S. 319, 322, 92 S. Ct. 1079, 31 L. Ed. 2d 263 (1972)*, and Plaintiff shall be "given the benefit of every favorable inference that can be drawn from those allegations." *Schrob v. Catterson, 948 F.2d 1402, 1405 (3d Cir. 1991)*. However, the plaintiff is required to make factual allegations and cannot rely on conclusory recitations of law. *Pennsylvania ex rel. Zimmerman v. Pepsico, Inc., 836 F.2d 173, 179 (3d Cir. 1988)*.

2. *Infringement*

Actavis's first argument is premised on their construction of certain terms in the **[*9]** patents. Actavis contends that there is no patent infringement because the patent claims themselves all use the term "non-direct compression filler." (Defs.' Br. 12). Actavis claims that the specifications of the patents "repeatedly state that the use of non-direct compression fillers is a feature of the invention, and that non-direct compression fillers are different and distinct from a [sic] direct compression fillers." (*Id.*). Actavis argues that under the ordinary meaning of the term "non-direct," a "non-direct compression filler" could not be construed as "direct compression filler," the type of filler used in the proposed Actavis product. (*Id.* at 12-13).

Because the court finds that "the proper time for this Court to address claim construction is not in a motion to dismiss[,]" *Schreiber v. Eli Lilly & Co., No. Civ. A. 05CV2616, 2006 U.S. Dist. LEXIS 13477, 2006 WL 782441, at *4 (E.D. Pa. 2006)* (citing *Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996))*, this argument fails.

Additionally, Actavis contends that during the prosecution of the *'392 patent*, Cima "represented to the PTO that its patent claims were limited to non-direct, as opposed to direct, **[*10]** compression fillers." (*Id.* at 12). Actavis claims that as a result of Cima's representations to the PTO, Cima is now estopped from asserting that direct compression fillers are equivalent to the claimed "non-direct compression fillers" under the doctrine of equivalents. (*Id.* at 15). Actavis contends that "[b]ecause Actavis' proposed products contains [sic] only direct compression fillers, they do not contain each and every element of the claims of the asserted patents." (*Id.*). Actavis asserts that as a result, its products do not infringe any of the asserted patent claims as a matter of law. (*Id.*).

Finally, Actavis contends that because the ANDA specifies the exact fillers that it will use in its products after FDA approval and the fillers fall outside of the claims of the patents, Actavis's proposed products do not infringe the patents. (Defs.' Br. 17). Actavis also argues that it is bound by the ANDA because "[i]f Actavis makes any misstatements in its ANDA under *21 U.S.C. § 335b(a)(1)*, it can be subject to civil penalties." (*Id.* at 17-18). Lastly, Actavis contends that because it must seek FDA approval for any changes to the ANDA, **[*11]** the products Actavis sells must conform with the information in the ANDA. (*Id.* at 18). Actavis argues that "this information demonstrates that Actavis' alprazolam products will not infringe the claims of the Cima *'981* and *'392 patents*." (*Id.*).

Actavis has attached several documents as exhibits to its motion. Included in those documents are: (1) Plaintiffs' response to an office action of the PTO rejecting claim 1 of the application that ultimately issued as the *'392 patent*; and (2) portions of the ANDA.

"As a general matter, a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings." *In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997)*. However, "a 'document *integral to or explicitly relied* upon in the com-

plaint' may be considered 'without converting the motion [to dismiss] into one for summary judgment.'" *Id.* (alteration in original) (quoting *Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1220 (1st Cir. 1996)).* "The rationale underlying this exception is that the primary problem raised by looking to documents outside the complaint-lack of notice to the plaintiff-is **[*12]** dissipated '[w]here plaintiff has actual notice . . . and has relied upon these documents in framing the complaint.'" *Id.* (alteration in original) (quoting *Watterson v. Page, 987 F.2d 1, 3-4 (1st Cir. 1993)).*

Here, Plaintiff's response to the PTO's office action is not integral to or explicitly relied upon in the Complaint. Therefore, this document will not be considered. Additionally, although Plaintiffs refer to the ANDA in the Complaint, the reference is merely to the fact that the ANDA was filed and to describe generally the contents of the ANDA that was gleaned from the Paragraph IV Notice Letter. Thus, because Plaintiffs did not explicitly rely on the ANDA document, the ANDA will not be considered on this motion. Furthermore, even if the ANDA was considered by the court, its filing by Actavis is not determinative of the infringement issue.

In support of their argument that the ANDA demonstrates that the fillers used in their proposed product fall outside of the claims of the patents, Actavis relies on *Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241 (Fed. Cir. 2000)* for the proposition that where the specification in the ANDA defines **[*13]** the product in a way that directly addresses the question of infringement, the ANDA applicant will be bound by that specification. However, although Actavis may be bound, this is not determinative of the infringement issue, especially on a motion to dismiss where issues of claim construction exist and where there has been little or no discovery. [2]

> 2 *Bayer* was decided on a motion for summary judgment.

"[I]n order to survive a motion to dismiss, 'a patentee need only plead facts sufficient to place the alleged infringer on notice.'" *Schreiber v. Eli Lilly & Co., No. Civ. A. 05CV2616, 2006 U.S. Dist. LEXIS 13477, 2006 WL 782441, at *4 (E.D. Pa. 2006)* (quoting *Phonometrics, Inc. v. Hospitality Franchise Sys., Inc., 203 F.3d 790, 794 (Fed. Cir. 2000)).* Here, Plaintiffs have alleged that Schwarz Pharma is the exclusive licensee to the patents and that Actavis has infringed the patents. Thus, Plaintiffs have pleaded sufficient facts to place Actavis on notice of their claims, and as a result, Actavis's **[*14]** motion will be denied. *See Schreiber, 2006 U.S. Dist. LEXIS 13477, 2006 WL 782441, at *4* (finding plaintiffs pleaded sufficient facts to put defendant on notice of their patent infringement claims).

B. *Actavis's Motion to Seal*

In its motion, Actavis seeks to seal portions of the memorandum of law in support of its motion to dismiss and certain exhibits of counsel's declaration in support of the motion to dismiss. This motion is unopposed.

Pursuant to *Local Civil Rule 5.3(c)*, a party may request to seal materials by filing a formal motion pursuant to *Local Civil Rule 7.1. L. Civ. R. 5.3(c)(1).* The motion papers must describe: (a) the nature of the materials or proceedings at issue; (b) the legitimate private or public interests which warrant the relief sought; (c) the clearly defined and serious injury that would result if the relief sought is not granted, and (d) why a less restrictive alternative to the relief sought is not available. *L. Civ. R. 5.3(c)(2).*

Counsel for Actavis has submitted a certification in support of this motion ("McShane Cert."). In the certification, counsel sets forth the nature of the of the materials as, *inter alia,* constituting or disclosing trade secrets **[*15]** and confidential and proprietary information. (McShane Cert. P 5). Counsel states that the action involves confidential technical information regarding a proposed product that Actavis has a legitimate interest in protecting. (*Id.* at P 7-8). Furthermore, counsel certifies that trade secrets would be lost if competitors gained access to the materials, which would result in a loss to Actavis. (*Id.* at P 10). Finally, counsel states that no less restrictive alternative is available to prevent the injury. (*Id.* at P 11).

The court finds that Actavis has satisfied the factors set forth in *L. Civ. R. 5.3(c)(2)* and therefore will grant the motion to seal.

C. *Cima's Motion to Consolidate*

Cima has moved to consolidate the Par case and the Actavis case pursuant to *Fed. R. Civ. P. 42(a). Rule 42(a)* provides:

> When actions involving a common question of law or fact are pending before the court, it may order a joint hearing or trial of any or all the matters in issue in the actions; it may order all the actions consolidated; and it may make such orders concerning proceedings therein as may tend to avoid unnecessary costs or delay. **[*16]** "

*Fed. R. Civ. P. 42(a).* "The purpose of consolidation is 'to streamline and economize pretrial proceedings so as to avoid duplication of effort, and to prevent conflicting outcomes in cases involving similar legal and factual

issues.'" *In re TMI Litig., 193 F.3d 613, 724 (3d Cir. 1999)* (quoting *In re Prudential Sec. Inc. Ltd. P'ships Litig., 158 F.R.D. 562, 571 (S.D.N.Y. 1994))*. The moving party bears the burden of proof on a motion for consolidation. *In re Consol. Parlodel Litig., 182 F.R.D. 441, 444 (D.N.J. 1998)*.

Although a common question of law or fact shared by the cases is a prerequisite for consolidation, the mere existence of common issues does not require consolidation. *Id.* "Once a common question of law or fact has been established, the decision to consolidate rests in the sound discretion of the district court." *Id.* The court, in exercising its discretion, "should weigh 'the interests of judicial economy against the potential for new delays, expense, confusion, or prejudice.'" *Id.* (quoting *Easton & Co. v. Mut. Benefit Life Ins. Co., 1992 U.S. Dist. LEXIS 10913, 1992 WL 448794, at *4 (D.N.J. Nov. 4, 1992)*). **[*17]** "In this analysis, however, '[c]onsiderations of convenience and economy must yield to a paramount concern for a fair and impartial trial.'" *Id.* (quoting *Johnson v. Celotex Corp., 899 F.2d 1281, 1285 (2d Cir. 1990))*.

Cima contends that the Par and Actavis cases should be consolidated because of the following similarities between the two cases: (1) the patents-in-suit are the same; (2) the plaintiffs are the same; (3) the two ANDAs at issue relate to the generic formulation of the same patented drug; (4) the legal issues relating to both infringement and validity will be the same; (5) both defendants assert noninfringement based on the materials and process used in creating the equivalent generic version; (6) the defendants' validity arguments will both involve consideration of the same prosecution history, prior art, and expert testimony; (7) *Markman* briefing and hearings will be directed to the same issues; and (8) the legal relief sought is the same. (Cima's Br. 5-7).

In support of its position, Cima relies primarily on *SmithKline Beecham Corp. v. Geneva Pharm., Inc., 2001 U.S. Dist. LEXIS 17434, 2001 WL 1249694 (E.D. Pa. 2001)*. In that **[*18]** case, defendant companies that manufactured generic drugs filed ANDAs for generic forms of the antidepressant drug PAXIL(R), which plaintiff alleged infringed on one or more of its patents. The court granted a motion to consolidate the several related actions for pretrial purposes. The court found that:

> Although the defendants have submitted five separate ANDAs for their generic formulations of the drug, there is substantial overlap among the patents they are alleged to have infringed. Issues of patent validity are therefore common to all defendants whose ANDA implicates a particular patent. Further, it does not appear that discovery in the earliest-filed actions is so far advanced that pretrial consolidation would be inefficient or prejudicial to the parties.

*2001 U.S. Dist. LEXIS 17434, [WL] *5.*

Additionally, Cima argues that judicial economy supports consolidation. (Cima's Br. 7). Cima contends that because of the similarities between the two cases, a significant portion of discovery will be the same, and a coordinated discovery plan will alleviate the need for duplicative discovery. (*Id.* at 8). Cima also contends that discovery in both cases is at an early and identical stage. Cima **[*19]** asserts that there has been no discovery in the Actavis case, and in the Par case, the only discovery has been the exchange of initial written discovery and objections. (*Id.*). Finally, Cima contends that consolidation minimizes the risk of conflicting results at trial and that the risk of any prejudice is minimal because consolidation assures consistent application of the facts and law in both cases. (*Id.* at 8-9).

Actavis sets forth several reasons for its opposition to consolidate. First, Actavis contends that the Par and Actavis cases likely involve different products and noninfringement positions. (Actavis's Br. 8). Although Actavis concedes that it doesn't know the details of Par's proposed products because that information is part of Par's confidential ANDA, Actavis argues that its own products do not infringe and that Par's products are likely more complicated and require additional discovery, given the schedule in the Par case. (*Id.*). Actavis contends that with different products likely at issue, the bases of noninfringement asserted by Actavis and Par will likely differ. (*Id.*).

Second, Actavis argues that the actions should not be consolidated because they **[*20]** are on two different discovery schedules. (*Id.* at 9). Actavis contends that: (1) in the Par case, fact discovery is set to close on May 21, 2007 and expert discovery to close in about six months; (2) while no discovery has commenced in the Actavis case, the Actavis case can progress more quickly than the Par case; (3) there has been minimal progress of discovery in the Par case; and (4) no motions to compel discovery have been filed by either party in the Par case. (*Id.*). Actavis argues that based on the discovery history, no party has demonstrated an intent to progress on a timely basis, and the discovery schedule is likely to be extended. [3]

> 3 Subsequent to the filing of Actavis's Opposition, by order dated May 23, 2007, the Magistrate Judge assigned to the Par case extended discovery to July 11, 2007.

Third, Actavis contends that the issues in the Actavis case are clear and can be disposed of quickly. (*Id.*). Actavis argues that its motion to dismiss makes it clear that its accused products do **[*21]** not infringe and that its noninfringement positions are clear and simple on both factual and legal grounds. (*Id.*). Actavis contends that it is prepared to provide discovery to Cima on an expedited basis which "will allow early disposition of the action, thereby avoiding extended, unnecessary discovery and promoting judicial economy." (*Id.* at 10).

Fourth, Actavis contends that consolidation would result in prejudice. Actavis argues that it will be prejudiced: (1) by extended, unnecessary, and costly discovery; (2) by tying the Actavis case to Par's schedule; and (3) if the concurrent motion to stay by Cima is also granted. (*Id.*).

Initially, the court finds that there is a common question of law or fact shared by the cases. Both cases involve the *'981* and *'392 patents* and ANDAs that were submitted by the Par/Kali Defendants and Actavis seeking the approval of the FDA necessary to engage in the commercial manufacture and sale of generic versions of NIRAVAM TM , an alprazolam product. Thus, the issues of infringement and validity will likely be similar. However, this does not end the inquiry, as the court is required to exercise its discretion in weighing "the interests of **[*22]** judicial economy against the potential for new delays, expense, confusion, or prejudice." *In re Consol. Parlodel Litig., 182 F.R.D. at 444.*

Here, the interests of judicial economy outweigh the potential for delays, expense, confusion, or prejudice. As discussed, the cases involve common questions of law and fact, which makes coordinated discovery appropriate. Similarly, consolidation will avoid duplication of efforts by the parties. Finally, although the Par case was filed earlier than the Actavis case, it does not appear that discovery has advanced to the point that consolidation would be inefficient or prejudicial to the parties. *See Smithkline,2001 U.S. Dist. LEXIS 17434, 2001 WL 1249694 at *5.* Therefore, Cima's motion to consolidate will be granted for pre-trial purposes.

D. *Cima's Motion to Stay*

Finally, Cima moves to temporarily stay the proceedings in both the Actavis case and the Par case. The district court's power to stay a proceeding "is incidental to the power inherent in every court to schedule disposition of the cases on its docket so as to promote fair and efficient adjudication." *Gold v. Johns-Manville Sales Corp., 723 F.2d 1068, 1077 (3d Cir. 1983)* **[*23]** (citing *Landis v. N. Am. Co., 299 U.S. 248, 254-55, 57 S. Ct. 163, 81 L. Ed. 153 (1936))*. This power "calls for the exercise of judgment, which must weigh competing interests and maintain an even balance[,]" *Landis, 299 U.S. at 254-55*, and includes "the authority to order a stay pending conclusion of a PTO reexamination." *Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1428 (Fed. Cir. 1988)* (citing *Gould v. Control Laser Corp., 705 F.2d 1340, 1342 (Fed. Cir. 1983))*. "The party seeking the stay must demonstrate 'a clear case of hardship or inequity, if there is even a fair possibility that the stay would work damage on another party.'" *Hertz Corp. v. The Gator Corp., 250 F. Supp. 2d 421, 424 (D.N.J. 2003)* (quoting *Gold, 723 F.2d at 1075-76*).

In deciding whether to grant a stay, the court must weigh the benefits against the costs and consider: (1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay would simplify the issues and the trial of the case; and (3) whether discovery is complete and/or a trial date has been set. *Motson v. Franklin Covey Co., No. Civ. 03-1067, 2005 U.S. Dist. LEXIS 34067, 2005 WL 3465664, at *1 (D.N.J. Dec. 16, 2005).*

**[*24]** The legislative history of the Patent Act of 1980 described the goal of the patent reexamination procedure as follows:

> Reexamination will permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation . . . . A new patent reexamination procedure is needed to permit the owner of a patent to have the validity of his patent tested in the patent office where the most expert opinions exist and at a much reduced cost . . . . The reexamination of issued patents could be conducted with a fraction of the time and cost of formal legal proceedings and would help restore confidence in the effectiveness of our patent system. The bill does not provide for a stay of court proceedings. It is believed by the committee that stay provisions are unnecessary in that such power already resides with the court to prevent costly pretrial maneuvering which attempts to circumvent the reexamination procedure. It is anticipated that these measures provide a useful and necessary alternative for challengers and for patent owners to test the validity of United States patents in an efficient and **[*25]** relatively inexpensive manner.

H.R. Rep. 96-1307(I) (Sept. 9, 1980).

Although the court is cognizant that the procedure may not operate as expeditiously as some may have expected, *see Rohm & Haas Co., 24 U.S.P.Q. 2d 1369, 1372 (D. Del. 1992)* (noting that a stay may add eighteen months to the time for resolution of the case), reexamination proceedings, including any appeal to the Board of Patent Appeals and Interferences, are to be conducted "with special dispatch." *35 U.S.C. § 305*. The term "special dispatch" has been found to "envision[] some type of unique, extraordinary, or accelerated movement." *Ethicon, 849 F.2d at 1426*.

At least one court has expressly noted that "there is a liberal policy in favor of granting motions to stay proceedings pending the outcome of USPTO reexamination or reissuance proceedings." *ASCII Corp. v. STD Entm't USA, Inc., 844 F. Supp. 1378, 1381 (N.D. Cal. 1994)*. This liberal policy exists in large part because of the "simplification of litigation that might result from the cancellation, clarification, or limitation of claims, and, even if the reexamination did not lead **[*26]** to claim amendment or cancellation, it could still provide valuable analysis to the district court." *Ethicon, 849 F.2d at 1428*; *see also, GPAC, Inc. v. D.W.W. Enters., Inc., 144 F.R.D. 60, 63 (D.N.J. 1992)* (finding PTO may be in better position to evaluate validity of patent and that reexamination procedure "was clearly intended to provide the federal courts with the expertise of the PTO.")

Here, Cima contends that a stay does not prejudice or tactically disadvantage defendants because in both the Actavis case and the Par case, defendants have not invested substantial time in the litigation. (Cima's Br. 4). Furthermore, Cima argues that any delay caused by the reexaminations will be minimal because not only is the PTO required to handle a reexamination with "special dispatch," but the patents in suit are well into the reexamination process. (*Id.* at 5). Cima contends that the patents have been in reexamination for approximately eighteen months and that the patentees' responses will be decided upon by the PTO examiner within the next four to six months. (*Id.*). Cima also argues that because during reexamination claims cannot be broadened and **[*27]** can only be narrowed, cancelled, or affirmed, staying the cases will not harm Actavis or Par. (*Id.* at 5-6). Cima contends that if the court does not enter a stay, the parties will have to litigate claims that may or may not exist following reexamination. (*Id.* at 6).

Additionally, Cima contends that there is no tactical disadvantage to defendants because discovery is in the early stages and no trial date has been set. (*Id.*). Furthermore, Cima contends that reexamination will simplify the issues in question and that awaiting the results of reexamination promotes judicial economy. (*Id.* at 7). Finally, Cima argues that the fact there has been no discovery in the Actavis case and very little discovery in the Par case weighs heavily in favor of grating a stay.

In opposition to Cima's motion to stay the proceedings, Par contends that a stay will result in prejudice and a tactical disadvantage. (Par's Br. 11). It explains that the nature of the litigation under the Hatch-Waxman Act implicates timing and delay concerns related to the 30-month stay of FDA approval. *See 21 U.S.C. § 355(j)(5)(B)(iii)* (approval by the FDA shall be made effective upon **[*28]** the expiration of the 30-month period beginning on the date of receipt of the notice that the ANDA containing a Paragraph IV Certification had been submitted to the FDA). (*Id.*). Par contends that because the FDA cannot approve Par's ANDA until 30 months from the date Par received its notice letter (September 22, 2008) or until the litigation is resolved in its favor, Cima's ability to continue the reexamination process ensures that the earlier of the two dates will be September 22, 2008. (*Id.*). Par argues that the result is a brand monopoly by Cima and Schwarz and a loss of revenue to Par. (*Id.*). Par also contends that although Cima states that the reexamination process will take another four to six months, that estimate does not take into account Cima's options to seek a reopening of the proceeding with the patent examiner, to appeal the decision to the Board, and to appeal the Board's decision to the Federal Circuit. (*Id.* at 12).

Additionally, Par argues that a stay will prejudice it by potentially exposing it to damages that would not exist if the case was resolved before the expiration of the 30-month stay. (*Id.*). Par contends that if Cima were to prevail in **[*29]** the litigation, the only damages available to Cima would be exceptional case attorney's fees because Par has not yet marketed a generic NIRAVAM TM product. (*Id.*). Par argues that if the litigation is ongoing after the 30-month period, Par will be faced with "the Hobson's choice of either marketing its product under a cloud of uncertainty and risking millions of dollars in potential liability, or refrain from marketing its product until the litigation has ended." (*Id.* at 12-13). Finally, Par contends that because the PTO has twice rejected Cima's patent claims, Cima has prevented Par from offering a generic NIRAVAM TM product. (*Id.* at 13). [4], [5], [6]

4 Par fails to address: (1) whether a stay would simplify the issues in the case; and (2) whether discovery is complete and/or a trial date has been set.

5 Par requests that if the court grants the motion to stay, that the court order that the stay of the action be conditioned on the shortening of the 30-month stay of FDA approval of Par's ANDA and that the order state that the stay does not toll the running of the 30-month stay of FDA approval.

Par cites *21 U.S.C. § 355(j)(5)(B)(iii)* which states, in part, that the court may shorten the 30-month stay if "either party to the action failed to reasonably cooperate in expediting the action . . ."

**[*30]**

6 Par also requests that if the court grants the motion to stay and Actavis's motion to dismiss, that it be granted leave to file a motion for summary judgment. Having denied Actavis's motion to dismiss, this argument is moot.

The court finds that factors weigh in favor of granting a stay. First, although Par may be prejudiced to some degree by a delay in the litigation, Par's argument that Cima will dictate the length of that delay is speculative. Additionally, any delay "would not be for such a protracted or indefinite period to constitute an abuse of discretion." *Motson, 2005 U.S. Dist. LEXIS 34067, 2005 WL 3465664, at *1* (citing *Gould, 705 F.2d at 1341-42*). Second, a stay pending reexamination would likely simplify the issues in both cases because it may result in the cancellation, clarification, or limitation of the claims. Similarly, given the expertise of the PTO, its findings would provide a valuable analysis to the court. Third, discovery is in its beginning stage in both cases with a trial date far from being set. Indeed, "[m]ost often, cases have been denied a stay due to the **[*31]** late stage of litigation, the fact that discovery was or would be almost completed, or the matter had been marked for trial." *GPAC, 144 F.R.D. at 64*. Here, none of those concerns are present.

Finally, although Par requests certain conditions on the stay, its reliance on *21 U.S.C. § 355(j)(5)(B)(iii)* is misplaced, and it fails to cite any case law to support its argument. Thus, Cima's motion to stay the proceedings will be granted.

## IV. *CONCLUSION*

For the reasons set forth above, Actavis's motion to dismiss will be denied and its motion to seal will be granted, and Cima's motion to consolidate and motion to stay will be granted. The court will enter an order implementing this opinion.

/s/ DICKINSON R. DEBEVOISE, U.S.S.D.J.

Dated: June 7, 2007

# TAB 2



**MARS, INCORPORATED, Plaintiff, v. JCM AMERICAN CORP., et al., Defendants.**

**Civil No. 05-3165 (RBK)**

**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY**

***2007 U.S. Dist. LEXIS 9819***

**February 13, 2007, Filed**

**NOTICE:** **[*1]** NOT FOR PUBLICATION

**SUBSEQUENT HISTORY:** Motion denied by *Mars, Inc. v. JCM Am. Corp., 2007 U.S. Dist. LEXIS 17351 (D.N.J., Mar. 9, 2007)*

**PRIOR HISTORY:** *Mars, Inc. v. JCM Am. Corp., 2006 U.S. Dist. LEXIS 84565 (D.N.J., Nov. 21, 2006)*

**CORE TERMS:** seal, confidential, declaration, purchase agreement, competitive, public interests, serious injury, restrictive alternative, reply brief, language used, substitution, disclosure, patent, sealed, common law, judicial proceedings, good cause, subsidiary, referenced, validators, lawsuit, secret, counterclaim, disadvantage, indemnity, machines, intends, reply

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For JCM AMERICAN CORP., JAPAN CASH MACHINE CO. LTD, Defendants: WILLIAM J. HUGHES, COOPER LEVENSON, ATLANTIC CITY, NJ.

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**JUDGES:** Joel Schneider, United States Magistrate Judge.

**OPINION BY:** Joel Schneider

**OPINION**

**OPINION AND ORDER TO SEAL**

This matter is before the Court on the unopposed Motion to Seal filed by plaintiff Mars, Incorporated ("Mars") [Doc. No. 68]. This motion will be decided on Mars's written submissions [Doc. Nos. 68, 69] and without oral argument pursuant to *Fed. R. Civ. P. 78* and *L. Civ. R. 7.1(b)(4)*. In addition to its Brief, Mars filed a Supplemental Revised Declaration from an authorized representative **[*2]** of the company.

The underlying complaint in this patent infringement action was filed on June 17, 2005. Plaintiff alleges defendants infringed its patents regarding component parts of document handlers, including bill validators used in vending machines, gaming machines, and similar devices requiring validation of paper currency. In their answer defendants asserted several affirmative defenses and a counterclaim. These include, *inter alia,* a claim that plaintiff and/or its attorneys engaged in inequitable conduct with the United Sates Patent and Trademark Office.

The present Motion to Seal arises in connection with plaintiff's Motion Under *Rule 25(c)* to Substitute MEI, Inc. for Mars, Incorporated [Doc. No. 63]. The essence of this motion is plaintiff's request to substitute MEI, Inc. ("MEI") for Mars as the named plaintiff in this lawsuit.

Mars claims that the entire interest in and to the Patents-In-Suit was transferred from Mars to MEI when it sold substantially all of the assets of MEI during the pendency of this litigation. Mars claims that when this lawsuit was filed it was the record owner of the Patents-In-Suit and MEI was a wholly owned subsidiary of Mars. Also, that **[*3]** MEI was licensed by Mars to manufacture and sell the bill validators covered by the Patents-In-Suit. (See Plaintiff's Brief at 2, Doc. No. 63-2). Mars alleges that the sale to MEI "provided for the assumption by MEI of any and all liabilities of Mars resulting from Mars's use or ownership of the purchased assets." Id. In addition, that Mars assigned to MEI "the entire right, title, and interest in and to the Patents-In-Suit. . . . Accordingly, the purchased assets included the Patents-In-Suit." Id.

Defendant opposed Mars's substitution motion and argued, in part, that Mars should have attached to its motion the contract between Mars and MEI. ("To put this [contract] into evidence, Mars must submit the document itself along with an authentication declaration, . . . ." (See Defendant's Brief at 4, Doc. No. 66-1). [1]

1 Defendants also argued, "Mars must provide the Agreement including the indemnifications from MEI to Mars as well as proof of MEI's financial ability to indemnify Mars under the counterclaims." Id. at 9.

**[*4]** In the near future Mars will file its reply brief in support of its substitution motion. In its reply Mars intends to refer to various agreements between Mars, MEI and third-parties. It also intends to "set forth a provision from a purchase agreement that it executed with a third-party purchaser in order to consummate the sale of its subsidiary MEI, Inc." (See January 29, 2007 Letter Brief at 1, Doc. No. 68). Mars will also attach and cite to portions of the purchase agreement with MEI that refer to assumed benefits and liabilities and indemnity issues. Id. at 2. These are the documents and references Mars wants to seal. The parties designated these documents as "Confidential -- Outside Counsel's Eyes Only" pursuant to the terms of a court approved Discovery Confidentiality Order. [Doc. No. 45]. The parties of course recognize that their agreement to keep a document confidential does not control whether the same document should be sealed.

It is well-established that there is "a common law public right of access to judicial proceedings and records." *In re Cendant Corp., 260 F.3d 183, 192 (3d Cir. 2001)*. This is consistent with well established precedent, **[*5]** based on *First Amendment* considerations and the common law right of access to judicial records, that documents filed with the court and judicial proceedings are open to the public. See *Nixon v. Warner Communications, Inc., 435 U.S. 589, 597, 98 S. Ct. 1306, 55 L. Ed. 2d 570 (1978)*; *FTC v. Lane Labs-USA, Inc., et al., C.A. No. 00-cv-3174(DMC), 2007 U.S. Dist. LEXIS 6430, *2 (D.N.J. 2007)*. Accordingly, when a party files a motion to seal of a "non-discovery nature" the moving party must demonstrate "good cause" for the protection of the material. *Pansy v. Borough of Stroudsburg, 23 F.3d 772, 786 (3d Cir. 1994)* (citations omitted). Courts generally protect materials containing "trade secret[s] or other confidential research, development, or commercial information" to prevent harm to a litigant's standing in the marketplace. See generally *Faulman v. Sec. Mut. Fin. Life Ins. Co., C.A. No. 04-5083 (AET), 2006 U.S. Dist. LEXIS 35875, 2006 WL 1541059, *1 (D.N.J 2006)*; see also *Fed. R. Civ. P. 26(c)(7)*.

Mars's request to seal is governed by *L. Civ. R. 5.3* which provides in pertinent part that a request to seal must be presented by motion. The **[*6]** motion papers must describe "(a) the nature of the materials or proceedings at issue, (b) the legitimate private or public interests which warrant the relief sought, (c) the clearly defined and serious injury that would result if the relief sought is not granted, and (d) why a less restrictive alternative to the relief sought is not available." See *L. Civ. R. **5.3 (c)(2)**. Rule 5.3* also provides that any order or opinion on any motion to seal "shall include findings on the factors set forth in (c)(2) . . . as well as other findings required by law . . . ." *L. Civ. R. **5.3 (c)(5)***. Pursuant to the requirements of the Local Rules, this Court will undertake to examine the factors in *Rule **5.3(c)(2)***(a) The Nature of the Materials or Proceedings at Issue

This has already been described. The materials at issue are confidential agreements involved in the transfer of the Patents-In-Suit from Mars to MEI.

(b) The Legitimate Private or Public Interests Which Warrant the Relief Sought

Mars asks to protect from disclosure the terms of various private agreements. Mars also alleges that according to the terms of its purchase agreement, Mars is contractually obligated to maintain **[*7]** secret trade information related to the sale of MEI. The Court finds that Mars has a legitimate private interest in keeping confidential the terms of a confidential business agreement not otherwise available to the public.

(c) The Clearly Defined and Serious Injury that Would Result if the Relief Sought is Not Granted

Mars alleges it will be seriously prejudiced if its motion is not granted because the "public disclosure of Mars's Confidential Information will dampen Mars's ability to negotiate effectively favorable terms on which it is willing to condition future sales and/or acquisitions." See February 7, 2007 Declaration of Raymond R. Castello, Esquire, P11. Mars also alleges absent an order to

seal it "will suffer a competitive injury by having its Confidential Information disclosed to the public". Id. The Court finds that this is a particularized showing of a serious injury that would result from disclosure. Mars should not have to sacrifice its competitive negotiating position in its business in order to effectively pursue its substitution motion. Mars also argues it will be injured if its motion to seal is denied because then it cannot refer to the actual documents **[*8]** at issue. The Court credits Mars's argument. If the actual language of the agreements in question is critical to the issue of whether MEI should be substituted for Mars, an issue this Court is not deciding at this time, Mars will be injured if it is prevented from filing a complete reply brief.

(d) Why a less Restrictive Alternative to the Relief Sought Is Not Available

Although there is no less restrictive alternative available than sealing the documents in question, the relief requested by Mars is too broad. Mars asks the court to seal the entirety of its reply brief and supporting Declaration. The Court believes that only the actual contract documents at issue and the specific language used therein should be sealed. The fact that the public may know about the mere existence of an indemnity agreement or assumption of liability provision between Mars and MEI does not create a competitive disadvantage for Mars. Only the revelation of Mars's actual agreements and the specific contractual language used therein would create a competitive disadvantage if revealed.

Accordingly, for all the foregoing reasons, good cause exists to grant Mars's Motion to Seal. The Court finds that **[*9]** Mars has met the elements in *L. Civ. Rule 5.3(c)(2)* and Mars's interest in protecting the referenced confidential business information outweighs the public interest in gaining access to the documents. Furthermore, the Court finds that no adverse impact will result to the public from the granting of Mars's motion.

Based upon the foregoing, it is hereby ORDERED this 13<th> day of February, 2007, that Mars's Motion to Seal [Doc. No. 68] is GRANTED in accordance with the terms of this Opinion and Order. The only portions of Mars's reply to defendants' opposition to its Rule 25(c) Motion that shall be sealed or redacted are the specific portions that refer to the actual language used in the documents referenced in this Order, and copies of the purchase agreements themselves. One complete copy of Mars's unredacted papers shall be sent directly to this Court in accordance with the applicable briefing schedule.

s/ Joel Schneider

United States Magistrate Judge

# TAB 3

FOCUS - 2 of 25 DOCUMENTS

**BRACCO DIAGNOSTICS, INC., Plaintiff, v. AMERSHAM HEALTH INC., et al., Defendants.**

**Civil Action No. 03-6025 (FLW)**

**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY**

***2006 U.S. Dist. LEXIS 75359*; *71 Fed. R. Evid. Serv. (Callaghan) 588***

**October 13, 2006, Decided**

**SUBSEQUENT HISTORY:** Motion denied by *Bracco Diagnostics v. Amersham Health Inc., 2007 U.S. Dist. LEXIS 98508 (D.N.J., May 3, 2007)*

**PRIOR HISTORY:** *Bracco Diagnostics Inc. v. Amersham Health Inc., 2005 U.S. Dist. LEXIS 26854 (D.N.J., Nov. 4, 2005)*

**CORE TERMS:** critical analysis, discovery, marketing, public interests, pharmaceutical, informal, prescription, work product, work product doctrine, self-critical, subjective, curtailed, audit, foods, correspondence, immunity, federal question, balancing test, disclosure, alternate, state law, in camera, public policy, remedial measures, non-production, preparation, privileged, testifying, evaluative, prong

**COUNSEL:** **[*1]** For BRACCO DIAGNOSTICS, INC., Plaintiff, Counter Defendant: ARNOLD B. CALMANN, SAIBER, SCHLESINGER, SATZ & GOLDSTEIN, LLC, NEWARK, NJ; ALBERT B. CHEN, KRAMER, LEVIN, NAFTALIS & FRANKEL, LLP, NEW YORK, NY US.

For AMERSHAM HEALTH INC., AMERSHAM HEALTH AS, AMERSHAM PLC, Defendants: CHARLES A. WEISS, KENYON & KENYON, NEW YORK, NY.

For AMERSHAM HEALTH INC., Counter Claimant:CHARLES A. WEISS, KENYON & KENYON, NEW YORK, NY.

**JUDGES:** HONORABLE TONIANNE J. BONGIOVANNI, UNITED STATES MAGISTRATE JUDGE.

**OPINION BY:** TONIANNE J. BONGIOVANNI

**OPINION**

**OPINION and ORDER ON INFORMAL MOTION**

**BONGIOVANNI, Magistrate Judge**

This matter comes before the Court upon informal motion of Plaintiff Bracco Diagnostics, Inc. (hereinafter "Bracco") to compel production of 1) documents concerning a sales and marketing audit performed by a third party and 2) communications between Defendants Amersham Health Inc., et al., (hereinafter "Amersham") and its expert. The documents in dispute have been provided to the court for *in camera* review. No oral argument was held pursuant to *Fed. R. Civ. P. 78*. For the foregoing reasons, Bracco's Motion to Compel production **[*2]** of documents concerning a sales and marketing audit performed by a third party shall be DENIED and the Motion to Compel production of communications between Amersham and its expert shall be DENIED.

**I. BACKGROUND**

The facts and procedural history of this matter are extensive and will not be repeated here at length. Presently before the Court is a Motion by Bracco to compel production of a sales and marketing audit performed by PricewaterhouseCoopers for Amersham (hereinafter "PWC report"). Amersham asserts that PriceWaterhouseCoopers was hired on behalf of Amersham's in-house counsel, to conduct "a review or assessment of certain of Amersham's sales and marketing practices [as] part of a compliance program designed to ensure that Amersham's practices were in accordance with the many

law and regulations that concern the marketing and sales of prescription pharmaceuticals." Declaration of Jeffrey Freedman in Opposition to Bracco's Motion to Compel (hereinafter "Decl. of Jeffrey Freedman") at P 3. Bracco claims that this audit did not concern or contain legal advice, privileged information, trial preparation information or information otherwise immune from discovery. July 19, 2006 Letter **[*3]** Brief in Support of Bracco's Informal Motion to Compel (hereinafter "Moving Brief") at 2. However, in their August 3, 2006 Reply Letter Brief in Further Support of Bracco's Informal Motion to Compel (hereinafter "Reply Brief), Bracco stipulated that the "real purposes of this **analysis** were... to meet government regulatory requirements ..." Reply Brief at 6.

Amersham claims that the PWC report is protected by the attorney client **privilege,** the work product immunity doctrine, and the **self critical analysis privilege.** See Amersham's July 28, 2006 Letter Brief in Opposition to Bracco's Informal Motion to Compel (hereinafter "Opposition Brief"). Bracco claims that none of these protections apply and the PWC report should be produced.

Bracco also moves for the production of "communications with Amersham's testifying expert." Moving Brief at 1. Amersham claims that the communication was between its expert, Dr. Schmid, and litigation counsel, and is therefore protected under the work product immunity doctrine. Opposition Brief at 5. Bracco asserts that the work product immunity doctrine is wholly inapplicable. Reply Brief at 7-8.

The PWC report and subject communication from Dr. Schmid **[*4]** to litigation counsel were submitted to the Court for *in camera* review.

## II. ANALYSIS

*Federal Rule of Civil Procedure 26(b)(1)* governs the scope of discovery in federal courts and provides that "[p]arties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action. . . ." Thus, *Rule 26(b)(1)* has been interpreted quite liberally, providing "a broad vista for discovery [which would] . . . 'encompass any matter that reasonably bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case.'" *Tele-Radio Sys. Ltd. v. Deforest Elec., Inc., 92 F.R.D. 371, 375 (D.N.J. 1981)* (citing *Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351, 98 S. Ct. 2380, 57 L. Ed. 2d 253 (1978)*). While not defined in the Rules, "privileged" is "generally understood to refer to those evidentiary **privileges** applicable at trial." *Robinson v. Magovern, 83 F.R.D. 79, 84 (W.D. Pa. 1979)*; see also *Martin v. Lamb, 122 F.R.D. 143, 145 (W.D.N.Y. 1988). Federal Rule of Evidence 501* **[*5]** sets forth the general rule with respect to the application of **privileges** in both federal question and diversity cases. It provides:

> Except as otherwise required by the Constitution of the United States or provided by Act of Congress or in rules prescribed by the Supreme Court pursuant to statutory authority, the **privilege** of a witness, person, government, State, or political subdivision thereof shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in light of reason and experience. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the **privilege** of a witness, person, government, State, or political subdivision thereof shall be determined in accordance with state law.

Hence, except in those situations governed by the second sentence of *Rule 501*, federal **privilege** law generally applies to federal question cases. See *Gannet v. First Nat'l State Bank of New Jersey, 546 F.2d 1072, 1076 (3d Cir. 1976)*, cert. denied, *431 U.S. 954, 97 S. Ct. 2674, 53 L. Ed. 2d 270 (1977)*. In federal questions cases that include pendant **[*6]** state law claims, "the federal rule favoring admissibility, rather than any state law **privilege,** is the controlling rule." *Wm. T. Thompson Co. v. General Nutrition Corp., 671 F.2d 100, 104 (3d Cir. 1982)*; *Wei v. Bodner, 127 F.R.D. 91, 94 (D.N.J. 1989)*; see also *Hancock v. Hobbs, 967 F.2d 462, 466-67 (11th Cir. 1992)*. The Court also notes that neither party disputes that federal common law controls the allegations of **privilege** applicable here.

A. Production of the PWC report

Amersham claims that the PWC report is protected by the **self critical analysis privilege,** attorney client **privilege,** and work product immunity. Because the Court has determined that the PWC report is protected under the **self critical analysis privilege,** the Court will not address Amersham's assertions of attorney client **privilege** and work product immunity. i. **Self Critical Analysis Privilege**

The **self critical analysis privilege,** or self evaluative **privilege,** has been recognized in a broad variety of cases in this District, in which the **privilege** is "essential to the free flow of information and ... the free flow of information is essential to promote recognized **[*7]** public interests." *Harding v. Dana Transp., Inc., 914 F. Supp. 1084 (D.N.J. 1996)*(citing Note, The **Privilege** of

**Self-Critical Analysis,** *96 HARV. L. REV. 1083, 1087 (1983)*). The **privilege** originated in Bredice v. Doctors Hospital, Inc., and was created to foster self-evaluation and the benefits derived therefrom. *50 F.R.D. 249, 250 (D.D.C. 1970)*, aff'd *156 U.S. App. D.C. 199, 479 F.2d 920 (D.C. Cir. 1973)*. The Bredice court recognized that "[c]andid and conscientious evaluation of clinical practices is a *sine qua non* of adequate hospital care...," and that "constructive professional criticism cannot occur in an atmosphere of apprehension that one doctor's suggestion will be used as a denunciation of a colleague's conduct in a malpractice suit." Id. "The value of **self critical** evaluations would be destroyed if not shielded from the discovery process." *Brunt v. Hunterdon Cty., 183 F.R.D. 181, 185 (D.N.J. 1998)*(citing *Bredice, 50 F.R.D. at 250*).

Although the **privilege** has been recognized in a broad range of cases, neither the United States Supreme Court nor the Third Circuit Court of Appeals **[*8]** have addressed the existence of a **self-critical analysis privilege.** However, "a federal court may resort to state law analogies for the development of a federal common law of **privileges** in instances where the federal rule is unsettled." *Brunt, 183 F.R.D. at 185* (quoting *Spencer Savings Bank, SLA v. Excell Mortgage Corp., 960 F. Supp. 835, 836 (D.N.J. 1997)* (internal quotations omitted)). Moreover, "[b]ecause the United States Supreme Court has cautioned federal courts against expanding federal **privileges,** ... rather than adopting a 'full fledged **privilege',** a case by case balancing approach is sufficient to address **self critical analysis** concerns." *Id. at 186*.

When analyzing whether the **self critical analysis privilege** is applicable, a court must balance (1) whether the information is the result of a **self critical analysis** undertaken by the party seeking protection, (2) the extent to which the information is available from other sources, (3) the degree of harm the litigant will suffer from the information's unavailability, (4) the possible prejudice to the party asserting the **privilege,** (5) the public interest in preserving the free flow of the **[*9]** type of information sought, and (6) whether the information is of the type whose flow would be curtailed if discovery were allowed. *U.S. v. Hackensack Univ. Med. Ctr., 2003 U.S. Dist. LEXIS 15225 at * 6-7 (D.N.J. August 13, 2003)*(citing *Brunt, 183 F.R.D. 181*).

*1. Is the PWC report the result of a **Self Critical Analysis***

To determine whether a report or document is the result of a **self critical analysis**, the Court must look at whether "(1) the material sought has been prepared for mandatory government reports or for a critical-self **analysis**" and (2) the **privilege** is being "extend[ed] only to subjective, evaluative materials, not to objective data." *Kopacz v. Delaware River and Bay Auth., 225 F.R.D. 494, 497 (D.N.J. 2004)*(citing *Melhorn v. N.J. Transit Rail Operations, Inc., 2001 U.S. Dist. LEXIS 6320, 2001 WL 516108 (E.D. Pa. May 15, 2001)*). The parties do not dispute that the contents of the report are subjective and evaluative in nature. However, Bracco argues that the "application of [the **self critical analysis privilege**] is generally limited to the context of hospital committee reports and equal opportunity forms submitted to the **[*10]** government, and thus is completely inapplicable here." Reply Brief at 5-6. This Court disagrees. In fact, the **self critical analysis privilege** has been extended to numerous areas besides medical care. See *Bradley v. Melroe Co., 141 F.R.D. 1 (D.D.C.1992)*(products liability); *In re Crazy Eddie Securities Litigation, 792 F. Supp. 197 (E.D.N.Y.1992)*(securities law); *Granger v. National R. Passenger Corp., 116 F.R.D. 507 (E.D.Pa.1987)*(railroad accident investigations); *Lasky v. American Broadcasting Cos., Inc., 5 Fed. R. Serv. 3d 1366 (S.D.N.Y. 1986)*(self-evaluative **privilege** exists in cases of violations of securities law, medical malpractice, violations of civil rights and libel); *N.Y. Stock Exch., Inc. v. Sloan, 22 Fed. R. Serv. 2d 500, 1976 U.S. Dist. LEXIS 13803 (S.D.N.Y.1976)*(accounting records); *Keyes v. Lenoir Rhyne College, 552 F.2d 579 (4th Cir. 1977)*, cert. denied, *434 U.S. 904, 98 S. Ct. 300, 54 L. Ed. 2d 190 (1977)* (academic peer reviews); *Lloyd v. Cessna Aircraft Co., 74 F.R.D. 518 (E.D.Tenn.1977)*(product safety assessments); *Banks v. Lockheed-Georgia Co., 53 F.R.D. 283 (N.D.Ga.1971)*(a defense **[*11]** contractor's confidential assessment of its equal employment opportunity practices).

The genesis of the law has created a rule where the "materials protected [by the **self critical analysis privilege**] have generally been those prepared for *mandatory government reports.*" *Harding, 914 F. Supp. at 1100* (emphasis in original). Amersham asserts that PricewaterhouseCoopers was hired on behalf of Amersham's in house counsel, to conduct "a review or assessment of certain of Amersham's sales and marketing practices [as] part of a compliance program designed to ensure that Amersham's practices were in accordance with the many law[s] and regulations that concern the marketing and sales of prescription pharmaceuticals." Decl. of Jeffrey Freedman at P 3. In other words, the PWC report was created to "assist counsel in advising the company on its compliance program in order to *best comply with the many laws and regulations* that concern the sales of prescription pharmaceuticals." Opposition Brief at 2 (emphasis added). Moreover, Bracco recognizes that the real purpose of the PWC report was "to meet government regulatory requirements" Reply Brief at 6. The Court is therefore **[*12]** satisfied that the PWC report was prepared to ensure compliance with governmental regulations and for a **self critical analysis**, and therefore the

Court looks to the second prong of the *Hackensack* **analysis.**

*2. Alternate Source*

The second prong of the balancing test looks to whether the subject information is available from an alternate source. Availability of an alternate or less-intrusive source has often been part of judicially developed balancing tests that weigh whether a **privilege** should apply or should be pierced. See *In re Kozlov, 79 N.J. 232, 244, 398 A.2d 882 (1979)* ("[T]here are necessary foundations to the valid piercing of any such **privilege** ... But it must also be shown ... [that] the information ... [c]ould not be secured from any less intrusive source.")(emphasis added).

In the instant matter, Amersham does not directly address whether the information contained in the PWC report is available from other sources. Bracco clearly states that "the report is not more easily available elsewhere." Reply Brief at 6. However, it is important to note that the PWC report contains subjective **analysis** and the "underlying information on which the report was based **[*13]** was available to Bracco in discovery." Opposition Brief at 4. Nevertheless, there is no alternate source for the **analysis** contained in the PWC report and therefore, this factor leans in favor of production.

*3 and 4. Prejudice to Bracco versus Prejudice to Amersham*

The third and fourth parts of the balancing test look to whether either party would be prejudiced from the information's unavailability or disclosure. See *Hackensack, 2003 U.S. Dist. LEXIS 15225 at * 7.* As can be expected, Bracco claims that it will be "seriously harmed by not obtaining the results of the audit," while Amersham argues that it "would likely be dissuaded from repeating such an investigation if the results could be used against it in litigation." See Reply Brief at 6; Opposition Brief at 4.

Amersham responds to Bracco's claim of prejudice by asserting that the information contained in the report is "marginally relevant (at best) to Bracco's claims." Opposition Brief at 4. Whereas, Bracco contends that the PWC report relates to Bracco's precise claims at issue in this litigation. Id. Bracco also asserts, in response to Amersham's claim of prejudice, that "[p]harmaceutical companies, as a matter **[*14]** of good routine, [and] good business practice, must constantly "self analyze" their practices[,] regardless of whether their practices become public, in order to act in compliance with various regulations, maintain their reputation, ensure patient safety and remain in business." Reply Brief at 6. On balance, the Court finds that Amersham would be prejudiced to a greater degree from disclosure of the information than Bracco would suffer from non-disclosure.

Amersham instituted an internal review following several complaints regarding marketing from Bracco. Opposition Brief at 1. This review resulted in the creation of the PWC report as part of an internal "compliance program designed to ensure that Amersham's practices were in accordance with the many laws and regulations that concern the marketing and sales practices of prescription pharmaceuticals." Decl. of Jeffrey Freedman at P 3. The internal compliance program was initiated "in contemplation of possible future claims or litigation involving such matters." Id.

Although Bracco speculates that the findings of the PWC report relate to its precise claims, they concede that they already have access to all of the factual information **[*15]** that forms the basis of the PWC report. Opposition Brief at 4. Cf. *Kopacz v. Delaware River and Bay Auth., 225 F.R.D. at 497* (holding that the **self critical analysis privilege** does not apply to factual or objective data). Moreover, Bracco's experts, including John S. Russell, had access to this factual information while rendering their expert opinions. See generally Decl. of John S. Russell at PP 1, 18-19; Opposition Brief at 4. While the Court recognizes that the availability of the factual documents does not wholly mitigate the prejudice to Bracco from non-production, it finds that because Bracco has access to the factual information underlying the PWC report, it would suffer less prejudice from non-production than Amersham would suffer from production. Thus, after balancing the prejudice to each party, these factors weigh in favor of Amersham.

*5. Public interest in flow of information*

The Court now turns to the "public interest in preserving the free flow of the type of information sought." See *Hackensack, 2003 U.S. Dist. LEXIS 15225 at * 8-9.* The information sought in the PWC report can be characterized as an independent review of Amersham's internal compliance **[*16]** program "in order to best comply with the many laws and regulations that concern the sales of prescription pharmaceuticals." Opposition Brief at 2. Amersham claims that "public interest supports encouraging companies to undertake efforts of this type." *2003 U.S. Dist. LEXIS 15225 at *4.* Bracco responds that "there is clearly a strong public interest in not allowing a pharmaceutical company to hide the results of investigations that show that it has willfully made false and misleading claims concerning the safety of its products to physicians, thereby compromising patient safety." Reply Brief at 6. After undertaking an *in camera* review, the Court finds that the PWC report was not the result of an "investigation", but rather was an internal check, prompted by complaints, to ensure Amersham's compli-

ance with all requisite law and regulations. Thus, the Court must determine what, if any, public interest exists in maintaining the free flow of information such as the PWC report.

Many courts have analogized the public's interest in maintaining the free flow of information of this type and invocation of the **self critical analysis privilege** to *Fed. R. Evid. 407*, more commonly **[*17]** known as the subsequent remedial measures rule. The rule provides, that when measures are taken after an event which would have made the event less likely to occur, evidence of the subsequent measures is not admissible to prove negligence at the event. *Fed R. Evid. 407*. Although the **self critical analysis privilege** should be analyzed under the evidentiary standards of *Rule 407*, Accord *Granberry v. Jet Blue Airways, 228 F.R.D. 647, 651 n.2 (N.D. Cal. 2005)*; *Stalling v. Union Pac. R.R. Co., 2003 U.S. Dist. LEXIS 9550, 2003 WL 21317297 at *10-11 (N.D. Ill. June 6, 2003)*; Cf. *Capellupo v. FMC Corp., 1988 U.S. Dist. LEXIS 3792, 1988 WL 41398 at *6 (D. Minn. May 3, 1988)*(utilizing *Rule 407* **analysis** to determine that **self critical analysis privilege** did not apply), the public policy considerations underlying *Fed. R. Evid. 407* are analogous to those underlying the development of the **self-critical privilege analysis** in this District and therefore worthy of discussion.

The public policy underlying *Rule 407* was articulated by the Third Circuit Court of Appeals in *Petree v. Victor Fluid Power, Inc., 831 F.2d 1191.* **[*18]** *Rule 407* is supported by "the social policy of encouraging people to take or at least not discourage them from taking, steps in furtherance of added safety." *Petree, 831 F.2d at 1198* (citing Notes on Advisory Committee on Proposed Rules). This is similar to the "policies underlying the **self critical analysis** doctrine [which] are based upon the need to promote candid and forthright self-evaluation." *Granger v. National R.R. Passenger Corp., 116 F.R.D. 507, 509 (E.D. Pa. 1987)*. "The **privilege** protects an organization or individual from the Hobson's choice of aggressively investigating accidents or possible regulatory violations, ascertaining the causes and results, and correcting the violations or dangerous conditions, but thereby creating a self-incriminating record that may be evidence of liability, or deliberately avoiding making a record on the subject (and possibly leaving the public exposed to danger) in order to lessen the risk of civil liability." *Reichhold Chemicals, Inc. v. Textron, Inc., 157 F.R.D. 522, 524 (N.D. Fl. 1994)*.

Other jurisdictions have also recognized the public policy link between the **self critical analysis [*19] privilege** and *Rule 407*. See *Reichhold Chemicals, Inc., 157 F.R.D. at 524* ("The **self-critical analysis privilege** is analogous to, and based on the same public policy considerations of *Rule 407, Federal Rules of Evidence*, which excludes evidence of subsequent remedial measures."); *Capellupo v. FMC Corp., 1988 U.S. Dist. LEXIS 3792, 1988 WL 41398 at *6 (D. Minn. May 3, 1988)*(The **self critical analysis privilege** "is perhaps most closely related to the philosophy of *Rule 407* "); *Martin v. Potomac Elec. Power Co., 1990 U.S. Dist. LEXIS 11688, 1990 WL 158787 (D. D.C. May 25, 1990)*(comparing *Rule 407* with the public policy reasons behind the development of the **self critical analysis privilege**). *Reid v. Lockheed Martin Aeronautics Co., 199 F.R.D. 379 n.2 (N.D. Ga. 2001)*(the **self critical analysis privilege** rests on many of the same policy considerations as does the exclusion of subsequent remedial measures).

Thus, the Court finds that it is in the public interest for organizations, when faced with a possible violation of law or government regulation intended to protect the public, to attempt to expeditiously determine the causes and results, and **[*20]** correct them accordingly. The flow of information of this type is crucial to protection of the public-at-large from so-called 'breakdowns in the system'.

In the instant matter, the PWC report was created as a result of Bracco' s complaints regarding Amersham's sales and marketing practices related to prescription pharmaceutical products. Opposition Brief at 1. The parties do not dispute that the sale and marketing of prescription pharmaceuticals is something regulated by the government for the public interest. See Food and Drug Administration's Mission Statement http://www.fda.gov/opacom/morechoices/mission.html (last visited October 10, 2006)(stating that "The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human ... drugs, biological products, medical devices ... [and] is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health."); See also *21 U.S.C. 355(a)* **[*21]** (Federal Food, Drug and Cosmetic Act outlining the Food and Drug Administration's regulatory authority). Amersham, through in house counsel Jeffrey Freedman, Esq., reacted to Bracco's complaints by engaging PricewaterhouseCoopers to help advise the company "in order to best comply with the many laws and regulations that concern the sales of prescription pharmaceuticals." Opposition Brief at 2. PricewaterhouseCoopers collected, analyzed and synthesized the requisite information and issued a subjective **analysis** of Amersham's sales and marketing practices, which has been dubbed the PWC report. [1] The Court views the report as a "step in furtherance of added safety." *Petree, 831 F. 2d at 1198*. Therefore, the Court finds that subjective **analysis** included in the PWC report is the type of

information whose free flow is in the public interest. Thus the fifth prong of the *Hackensack* test is resolved in favor of Amersham.

1 The Court notes that it has not made any findings regarding what conclusions were reached in the PWC report, nor whether the PWC report was utilized in any way by Amersham.

**[*22]** *6. Curtailing of flow of information*

The Court finally looks to whether the information is of the type whose flow would be curtailed if discovery were allowed. See *Hackensack, 2003 U.S. Dist. LEXIS 15225 at *9*. The Court has recognized that the purpose of the **self critical analysis privilege** includes avoiding "the chilling effect upon such self **analysis** which would result from complete disclosure." *Todd v. South Jersey Hosp. Sys., 152 F.R.D. 676, 682 (D.N.J. 1993)*. As previously mentioned, the Court finds that there is a substantial likelihood that the flow of the information at issue would be curtailed if discovery is allowed. Bracco argues that for the same reasons mentioned under the fifth factor above, "the information is not of a scope whose flow would be curtailed if discovery were allowed." Reply Brief at 6. However, the Court has already distinguished Bracco's broad assertions from the instant set of facts. Allowing discovery would perpetuate a chilling effect, and create the Hobson's choice discussed in *Reichhold Chemicals, 157 F.R.D. at 524*, where an organization would expose itself to civil liability if they choose to investigate **[*23]** and correct violations or dangerous conditions. Therefore the Court finds that the sixth factor of the *Hackensack* test balances in Amersham's favor.

ii. Application of Balancing Test

After applying the factors outlined in *Hackensack*, the Court finds that the PWC report is protected by the **self critical analysis privilege.** The Court has found that the **privilege** is applicable to the PWC report, that Amersham would suffer more prejudice from the reports release than Bracco would face from non-production, and that there are extremely strong public interests in protecting the free flow of information of this type, and ensuring that the flow of the information is not curtailed. Therefore, Bracco's informal Motion to Compel production of the PWC report is denied.

B. Correspondence from Dr. Schmid

Bracco has also requested that Amersham be compelled to produce a communication between Amersham and one of Amersham's testifying experts, Dr. Christopher Schmid (hereinafter "Schmid"). Moving Brief at 3. Bracco asserts that under *Fed. R. Civ. P. 26(a)(2)(B)*, "a party must **disclose** all information provided to its testifying expert for consideration **[*24]** in the expert's report, including information protected by the attorney-client **privilege** or the work product **privilege**." *Synthes Spine Co. v. Walden, 232 F.R.D. 460, 464 (E.D. Pa. 2005)*. Amersham argues that the communication to Schmid is protected by the work product doctrine. Opposition Brief at 5. Amersham also asserts that prior to these communications, the parties had stipulated "that neither side would seek drafts of expert reports or communications with experts concerning preparation of expert reports, including documents exchanged between counsel and experts." Opposition Brief at 4 n.2.

1. Work Product Doctrine

The work product **privilege** is uniformly governed by *Fed. R. Civ. P. 26(b)(3)* in both federal question and diversity cases. *United Coal Cos. v. Powell Construction Co., 839 F.2d 958, 966 (3d Cir. 1988)*. *Fed. R. Civ. P. 26(b)(3)* states, in part, that "the court shall protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party concerning the litigation." *Fed. R. Civ. P. 26(b)(3)* **[*25]** . To overcome the work product doctrine, a party must demonstrate "a substantial need of the materials in preparation of that party's case." Id. The party must also make a showing of "undue hardship to obtain the substantial equivalent of the materials by other means." Id. "Even if those requirements are met, the court will still withhold documents that would **disclose** mental impressions, conclusions or legal theories of an attorney or other representative of a party concerning a lawsuit." *Coregis Ins. Co. v. Law Offices of Carole F. Kafrissen, P.C., 57 Fed. Appx. 58, 60 (3d Cir. 2003)*(citing *Fed. R. Civ. P. 26(b)(3)*)(internal quotations omitted). *Rule 26(b)(3)* also "provides work product protection independently of *Rule 26(b)(4)(B)*" *In re Cendant Corp. Securities Litig., 343 F.3d 658, 664-65 (3d Cir. 2003)*.

After conducting an *in camera* review of the correspondence, the Court finds that Dr. Schmid did not review, reflect upon, read, or use this communication in formulating his conclusions regarding Dr. Solomon's work. The Court also confirms that the correspondence contains information sent from Dr. **[*26]** Schmid to litigation counsel. This Court determines that this correspondence is protected by the work product doctrine. Bracco's Informal Motion to Compel the correspondence from Dr. Schmid is therefore denied.

**III. CONCLUSION and ORDER**

For the aforementioned reasons and for good cause shown,

IT IS on this 13th day of October, 2006,

ORDERED that Bracco's Informal Motion to Compel discovery of the PWC Report is DENIED as the PWC Report is protected by the **self-critical analysis privilege;** and it is further

ORDERED that Bracco's Informal Motion to Compel discovery of a communication between Dr. Schmid and litigation counsel is DENIED as the communication is protected under the work product doctrine.

s/ **HONORABLE TONIANNE J. BONGIOVANNI**

**UNITED STATES MAGISTRATE JUDGE**